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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,169	11/12/2002	Shaomeng Wang	P 0280714	9701
909	7590	09/07/2004	EXAMINER	
PILLSBURY WINTHROP, LLP			CHANG, CELIA C	
P.O. BOX 10500				
MCLEAN, VA 22102			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,169

Applicant(s)

WANG ET AL.

Examiner

Celia Chang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 14 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 25-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 25-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. Amendment and response filed by applicants dated June 14, 2004 have been entered and considered carefully. All previous claims i.e. 1-24 have been canceled. New claims 25-33 are pending.

2. The rejection of claim 1 under 35 USC 112 second paragraph and first paragraph is maintained for reason of record.

Applicants' argument that "Thus when R3 is a covalent bond as defined, the structure is a fused ring structure, including an O atom from R2" does not find descriptive and enabling support from the specification. Please note that when the fusing is between the OH moiety of R3 and the OH moiety of R2, it forms a peroxide, while when fusing is between the OR'''' of the R3 and OH of the R2, it is a dioxlene etc. Therefore, no descriptive support nor enablement was found in the specification. The only species supporting such a fusion is compound 11 which has been disclosed to be "data taken from reference 54" (see page 31 specification), thus, is not novel. If this is the only fused ring structure applicants are referring to, then, applicants are urged to provide the anticipatory compound from reference 54 under 37 CFR § 1.105.

Therefore, it is unclear "what" is this structure (2<sup>nd</sup> paragraph) and how it can be made with what starting material (first paragraph). The rejection is proper and maintained.

3. The rejection under anticipation over the enormous references as recited in section 3 page 4 of the previous office action is maintained for reason of record. The structural delineation will not be provided again. Clear anticipation over claims 25, 27-28 with structural delineation does not required detail explanation. Applicants have not limited the R2 being optionally substituted phenyl carbonyl, R4 being optionally substituted phenyl and R3 is F, Cl, Br, I, OH, OR'''' or OC=OR'''' to obviate the rejection. No rebuttal was made by applicants.

4. The rejection of claims 1-2 under 35 USC 102(a) or (b) over US 2,489,669, 3,408,445, 3,965,104, 3,887,568, 3,591,593, CA74, 130, 52 or 63 are applicable to claims 25, 27-28 and are maintained for reason of record.

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Applicants' argument is that formula (I) are drawn to stereoconfiguration not racemic mixtures. This is erroneous. Please note that "stereoconfiguration" must be described and notated as "R" and "S" at the stereocenter. Attorney's allegation that the dotted or wedged bonds are representing stereoconfiguration is erroneous. Please note that not only no description or nomenclature to any "R" or "S" stereoisomer was found in the specification, but also none of the compounds named in claim 26 is a stereoisomer. Further, the dotted or wedged bonds are not defining stereoisomeric forms can be understood by comparing the same structural dotted or wedged bonding in two compounds of CA140:423555 and CA118:99881 but having *opposite* stereo configuration, one is 3S,4R-piperidine, while another is 3R,4R -piperidine. Therefore, the allegation that claim 1 is stereoconfiguration compounds lacks both descriptive support from the specification as well as well known chemical nature for such properties.

The claims are thus, all drawn to racemic compounds and anticipation was found.

5. The rejection of claims 1-9 which are now applicable to newly submitted claims 25-33, under 35 USC 102(f) over CA 133:66179, 133:171745 or 135:339052, is maintained for reason of record.

Applicant's argument is that the authorship of the first two article does not overlap with the instant application. While the instant applicants' claims included the specific compounds of the first two article, no specific disclosure in the specification to the species owned and used by the two reference can be found. Therefore, the attorney offered no basis for supporting the argument that the instant inventor "did" independently conceive of and reduce to practice the subject matter. Please note that each species under a Markush claim is an independent invention. When "another" owned and used some of the species for which applicants did not disclose or make, the question of who is the "first" to invent the generic concept must be resolved. The scope of the generic concept being supportive by the specification to an "independently conceive of and reduce to practiced" subject matter should be contemplated.

The third reference has a "different" inventorship with some overlap with the instant application. Applicants argue that this reference is published after the filing date. Please note that the statute of 102(f) does not have a "prior" date requirement. Attorneys are urged to consult MPEP § 2137.

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6. The rejection of claims 1-9, which is now applicable to the newly presented claims 25, 27-28 under 35 USC 102(b) over US 5,512,584 is maintained for reason of record.

Applicants' argument is the same as that of section 4, that the prior art compound is racemic. The same finding in section 4 is also applicable here and incorporated by reference.

7. The rejection of claims 1-9, which is now applicable to claims 25-33, over Steiner et al. '584 in view of Casy, Yanai and Foy is maintained for reason of record.

Again, applicants argued that the reference was racemic and the claims are stereoconfiguration is erroneous. The same finding in section 4 is also applicable here and incorporated by reference.

8. The newly added claims 25-33 are subject to the following new grounds of rejection:

A) Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicants regard as their invention because in the claims the parameter R3 was not defined.

B) Claims 29-30, 32-33 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicants regard as their invention because it is unclear what does the term "an analog thereof" is referring to. No specific definition can be found in the specification as to a defined scope for this term. To the extent that the term interpreted to the broadest sense will be anything related to the compound as claimed, the above 102 and 103 rejections (sections 4, 5, 6 and 7) are applicable and hereby incorporated by reference.

In addition, claims 29-33 are dependent on the **canceled** claim 4 which is improper.

C) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al. CA 42:4538 in view of Thiele et al. CA 70 and Thiele et al. US 3,591,593.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Foster et al. CA 42 disclosed analogous compounds as the instant claims which have the same activity as the claimed compounds being morphine like i.e. cocaine abuse. A structural very close species is delineated as RN5409-66-5.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference of the delineated species from the species claims 29-33 is that instead of unsubstituted phenyls, the claims are drawn to compounds having halogen or methyl substitution. Thiele et al. CA 70 taught that structural analogous compounds of the claims have multiple activity and analgesic or coronary blood flow activity are among the many activities for such compounds. Thiele et al. '593 taught that substitution on the phenyl ring with such structural analogous compounds (see col. 1 lines 50-55) is optionally halogen or methyl. In addition, the optical isomers can be separated and used with expected similar activity (see col. 3, lines 32-37).

*Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)*

One having ordinary skill in the art is deemed to be aware of all the pertinent art in the field. The above references placed the analogous compounds of the claims having the same utility in the possession of artisan in the field. The difference between the claimed species and the prior art species differ in methyl group replacing a hydrogen atom on the phenyl ring not only is a well recognized feature within the sphere of obviousness that surrounds the teaching of the prior art compounds (In re Wood 199 USPQ 137), but also a well recognized feature to be considered an optional choice of modification for such compound clearly delineated in analogous art (two Thiele references). In absence of a showing of unexpected results, there is nothing unobvious in replacing hydrogen atoms of the prior art compound with well delineated optional choices of substituents in their optically separated form which have been clearly suggested by the analogous art to have expected and successful same utility.

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9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Aug. 31, 2004

  
Celia Chang  
Primary Examiner  
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